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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/402,564	01/27/00	LOUVEL	F P1047/20008

HM22/0601  
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EXAMINER

PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

06/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt is acknowledged of the Information Disclosure Statement, and the Declaration, received January 27, 2000.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 refers to the figures, rather than specifically claiming the invention. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,594,470 to Borodkin (hereinafter US '470). US '470 discloses a tablet including coated particles. In column 2, lines 51-65, US '470 teaches that the drug/resin particles are coated with HPMC, which applicant teaches on page 12 of the

specification can act as the disintegrating agent in their claimed invention. US '470 does not teach the same process as claimed by applicant to produce the particles. However, according to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985).

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/14058 to Ohslack *et al.* (hereinafter WO '058). WO '058 teaches a sustained release dosage form comprising a plurality of microparticles produced via melt extrusion techniques (abstract), and WO '058 also discusses the extruder used to make the formulation. WO '058 teaches that the active ingredient in the formulation is in a matrix including a hydrophobic material, such as alkylcelluloses and acrylic polymers, and a hydrophobic carrier (p 6, l 13-30). However, WO '058 further teaches that a plasticizer can also be added to help with the extrusion process (p 10, l 21-26). WO '058 also teaches a method for preparing their formulation, which involves blending the drug with the matrix ingredients, heating the blended mixture, placing the mixture in the extruder, extruding the strands, then dividing the strands into the desired pieces, such as pellets (p 7, l 15-30, and claim 18). WO '058 also teaches that the extruded materials can be cut into multiparticulates by any means known in the art, and they further teach that the

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multiparticulates can be compressed into tablets (p 8, l 1-2). Lastly, WO '058 teaches that the exit port of the extruder can be any desired shape, in order to make the multiparticulates the desired shape and size (p 17, l 23-25). It is the position of the examiner that this disclosure reads on the method of making particles as claimed by applicant.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3, 594, 470 to Borodkin as applied to claims 1 and 2 above. US '470 does not specifically disclose that the active ingredient be in a thermoplastic material, but they do disclose that the particle comprising the active contains a resin. It is the position of the examiner that US '470 is a generic teaching of coated particles, which are then compress into tablets to oral administration of an active ingredient.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WP 96/14058 to Oshlack *et al* as applied to claims 3 and 4 above. Although WO '058 does not teach that the particles are spheroidal, they do teach that the exit port of the extruder can be any shape desired. They further teach that they want to eliminate the

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spheronization step, which is stated by applicant as well, and it is the position of the examiner that by allowing the exit port of the extruder to be any shape so that the multiparticulates can be of any shape, this allows the exit port to be a shape that would form spheroidal particulates. In addition, applicant states that the particles are preferably spheroidal, which does not necessarily require that they be spheroidal. Further, although WO '058 does not specifically refer to a maturing step, it is the position of the examiner that the heating step prior to extrusion, which is discussed by WO '058, reads on applicant's claimed maturing step.

In addition, WO '058 does not teach that the particles are coated. However, it is the position of the examiner that coated particles are well known to those of ordinary skill in the pharmaceutical art, and further binders and disintegrants such as hydroxypropylmethyl cellulose are well known as pharmaceutical additives. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the particles as disclosed by WO '058 with a disintegrant, especially if quicker release is desired. Disintegrants are well known in the pharmaceutical art to facilitate breakup and dissolution of pharmaceutical formulations after administration, which would obviously quicken release time. (see Remington's Pharmaceutical Sciences, page 1627).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E Pulliam  
Art Unit 1615  
May 25, 2000

THURMAN K. PAGE  
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